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EXAMINER	
TANG, KAREN C	

ART UNIT	PAPER NUMBER
2151	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/996,475	OLCHANSKI ET AL.	
	Examiner	Art Unit	
	Karen C. Tang	2151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

- This action is responsive to the amendment and remarks file on 10/23/07.
- Claims 1-21, and 23-25 are presented for further examination.

DETAILED ACTION

Response to Arguments

1. Claims 1-21, and 23-25 have been examined.

2. Applicant's arguments filed 10/23/07 have been fully considered but they are not persuasive.

Affidavit

3. The affidavit filed on 05/25/07 under 37 CFR 1.131 has been considered but is ineffective to overcome the Menzie et al. reference.

The declaration filed on 05/25/07 fails to provide evidence to support the indicated claim of conception prior to the effective date of the Menzie reference. The evidcnt is not enough to satisfy issues of diligence or conception reduction to practice or an actual reduction to practice.

4. Applicant is attempt to prove the invention by showing conception before May 15, 2000 (the effective data of Menzie) before that date until Nov 20, 2001, the date of filing of this application.

5. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Menzie reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The exhibit does not demonstrate the

evidence or proof in showing that the claimed conception took place. Applicant has not yet support each of claim element with the affidavit to demonstrate conception. Applicant must point out where each claimed limitation is according to the affidavit on record.

Applicant has provided the same 23 pages from the affidavit for mapping all the limitations without explaining how these pages are relevant to the claim limitations. Applicant needs to map the limitation by point to a specific page and line number on the affidavit in order to demonstrate the conception. Applicant needs to also apply the mapping on all the dependent claims, or else the depending claims cannot receive the benefit of priority date supported by the affidavit.

6. Applicant has not demonstrated the reasonable diligence from the period of May 15, 2000, to November 21, 2000.

7. Applicant has not demonstrated the reasonable diligence from the period of November 30, 1998, to March 31, 1999.

8. Applicant has not demonstrated the reasonable diligence from the period of March 1999, to July 2000.

9. Applicant has not demonstrated the reasonable diligence from the period of August 4, 1999, to September 24, 2000.

2138.06 [R-1] "Reasonable Diligence"

The diligence of 35 U.S.C. 102(g) relates to rea-sonable "attorney-diligence" and "engineering-diligence" (*Keizer v. Bradley*, 270 F.2d 396, 397, 123 USPQ 215, 216 (CCPA 1959)), which does not require that "an inventor or his attorney ... drop all other work and concentrate on the particular invention involved...." *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974).

CRITICAL PERIOD FOR ESTABLISHING DILIGENCE BETWEEN ONE WHO WAS FIRST TO CONCEIVE BUT LATER TO REDUCE TO PRACTICE THE INVENTION

The critical period for diligence for a first conceiver but second reducer begins not at the time of conception of the first conceiver but just prior to the entry in the field of the party who was first to reduce to practice and continues until the first conceiver reduces to practice. *Hull v. Davenport*, 90 F.2d 103, 105, 33 USPQ 506, 508 (CCPA 1937) ("lack of diligence from the time of conception to the time immediately preceding the conception date of the second conceiver is not regarded as of importance except as it may have a bearing upon his subsequent acts"). What serves as the entry date into the field of a first reducer is dependent upon what is being relied on by the first reducer, e.g., conception plus reasonable diligence to reduction to practice (*Fritsch v. Lin*, 21 USPQ2d 1731, 1734 (Bd. Pat. App. & Inter. 1991), *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974)); an actual reduction to practice or a constructive reduction to practice by the filing of either a U.S. application (*Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975)) or reliance upon priority under 35 U.S.C. 119 of a foreign application (*Justus v. Appenzeller*, 177 USPQ 332, 339 (Bd. Pat. Inter. 1971) (chain of priorities under 35 U.S.C. 119 and 120, priority under 35 U.S.C. 119 denied for failure to supply certified copy of the foreign application during pendency of the application filed within the twelfth month)).

THE ENTIRE PERIOD DURING WHICH DILIGENCE IS REQUIRED MUST BE ACCOUNTED FOR BY EITHER AFFIRMATIVE ACTS OR ACCEPTABLE EXCUSES

An applicant must account for the entire period during which diligence is required. *Gould*

v. Schawlow, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); *In re Harry*, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964) (statement that the subject matter "was diligently reduced to practice" is not a showing but a mere pleading). A 2-day period lacking activity has been held to be fatal. *In re Mulder*, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131 issue); *Fitzgerald v. Arbib*, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959) (Less than 1 month of inactivity during critical period. Efforts to exploit an invention commercially do not constitute diligence in reducing it to practice. An actual reduction to practice in the case of a design for a three-dimensional article requires that it should be embodied in some structure other than a mere drawing.); *Kendall v. Searles*, 173 F.2d 986, 993, 81 USPQ 363, 369 (CCPA 1949) (Diligence requires that applicants must be specific as to dates and facts.).

The period during which diligence is required must be accounted for by either affirmative acts or acceptable excuses. *Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975); *Rieser v. Williams*, 225 F.2d 419, 423, 118 USPQ 96, 100 (CCPA 1958) (Being last to reduce to practice, party cannot prevail unless he has shown that he was first to conceive and that he exercised reasonable diligence during the critical period from just prior to opponent's entry into the field); *Griffith v. Kanamaru*, 816 F.2d 624, 2 USPQ2d 1361 (Fed. Cir. 1987) (Court generally reviewed cases on excuses for inactivity including vacation extended by ill health and daily job demands, and held lack of university funding and personnel are not acceptable excuses.); *Litchfield v. Eigen*, 535 F.2d 72, 190 USPQ 113 (CCPA 1976) (budgetary limits and availability of animals for testing not sufficiently described); *Morway v. Bondi*, 203 F.2d 741, 749, 97 USPQ 318, 323 (CCPA 1953) (voluntarily laying aside inventive concept in pursuit of other projects is generally not an acceptable excuse although there may be circumstances creating exceptions); *Anderson v. Crowther*, 152 USPQ 504, 512 (Bd. Pat. Inter. 1965) (preparation of routine periodic reports covering all accomplishments of the laboratory insufficient to show diligence); *Wu v. Jucker*, 167 USPQ 467, 472-73 (Bd. Pat. Inter. 1968) (applicant improperly allowed test data sheets to accumulate to a sufficient amount to justify interfering with equipment then in use on another project);

Tucker v. Natta, 171 USPQ 494,498 (Bd. Pat. Inter. 1971) ("[a]ctivity directed toward the reduction to practice of a genus does not establish, *prima facie*, diligence toward the reduction to practice of a species embraced by said genus"); *Justus v. Appenzeller*, 177 USPQ 332, 340-1 (Bd. Pat. Inter. 1971) (Although it is possible that patentee could have reduced the invention to practice in a shorter time by relying on stock items rather than by designing a particular piece of hardware, patentee exercised reasonable diligence to secure the required hardware to actually reduce the invention to practice. "[I]n deciding the question of diligence it is immaterial that the inventor may not have taken the expeditious course....").

WORK RELIED UPON TO SHOW REASONABLE DILIGENCE MUST BE DIRECTLY RELATED TO THE REDUCTION TO PRACTICE

The work relied upon to show reasonable diligence must be directly related to the reduction to practice of the invention in issue. *Naber v. Cricchi*, 567 F.2d 382, 384, 196 USPQ 294, 296 (CCPA 1977), *cert. denied*, 439 U.S. 826 (1978). >See also *Scott v. Koyama*, 281 F.3d 1243, 1248-49, 61 USPQ2d 1856, 1859 (Fed. Cir. 2002) (Activities directed at building a plant to practice the claimed process of producing tetrafluoroethane on a large scale constituted efforts toward actual reduction to practice, and thus were evidence of diligence. The court distinguished cases where diligence was not found because inventors either discontinued development or failed to complete the invention while pursuing financing or other commercial activity.); *In re Jolley*, 308 F.3d 1317, 1326-27, 64 USPQ2d 1901, 1908-09 (Fed. Cir. 2002) (diligence found based on research and procurement activities related to the subject matter of the interference

count).< "[U]nder some circumstances an inventor should also be able to rely on work on closely related inventions as support for diligence toward the reduction to practice on an invention in issue." *Ginos v. Nedelec*, 220 USPQ 831, 836 (Bd. Pat. Inter. 1983) (work on other closely related compounds that were considered to be part of the same invention and which were included as part of a grandparent application). "The work relied upon must be directed to attaining a reduction to practice of the subject matter of the counts. It is not sufficient that the activity relied on concerns related subject matter." *Gunn v. Bosch*, 181 USPQ 758, 761 (Bd. Pat. Inter. 1973) (An actual reduction to practice of the invention at issue which occurred when the inventor was working on a different invention "was fortuitous, and not the result of a continuous intent or effort to reduce to practice the invention here in issue. Such fortuitousness is inconsistent with the exercise of diligence toward reduction to practice of that invention." 181 USPQ at 761. Furthermore, evidence drawn towards work on improvement of samples or specimens generally already in use at the time of conception that are but one element of the oscillator circuit of the count does not show diligence towards the construction and testing of the overall combination.); *Broos v. Barton*, 142 F.2d 690, 691, 61 USPQ 447, 448 (CCPA 1944) (preparation of application in U.S. for foreign filing constitutes diligence); *De Solms v. Schoenwald*, 15 USPQ2d 1507 (Bd. Pat. App. & Inter. 1990) (principles of diligence must be given to inventor's circumstances including skill and time; requirement of corroboration applies only to testimony of inventor); *Huelster v. Reiter*, 168 F.2d 542, 78 USPQ 82 (CCPA 1948) (if inventor was not able to make an actual reduction to practice of the invention, he must also show why he was not able to constructively reduce the invention to practice by the filing of an application).

DILIGENCE REQUIRED IN PREPARING AND FILING PATENT APPLICATION

The diligence of attorney in preparing and filing patent application inures to the benefit of the inventor. Conception was established at least as early as the date a draft of a patent application was finished by a patent attorney on behalf of the inventor. Conception is less a matter of signature than it is one of disclosure. Attorney does not prepare a patent application on behalf of particular named persons, but on behalf of the true inventive entity. Six days to execute and file application is acceptable. *Haskell v. Coleburne*, 671 F.2d 1362, 213 USPQ 192, 195 (CCPA 1982). See also *Bey v. Kollonitsch*, 866 F.2d 1024, 231 USPQ 967 (Fed. Cir. 1986) (Reasonable diligence is all that is required of the attorney. Reasonable diligence is established if attorney worked reasonably hard on the application during the continuous critical period. If the attorney has a reasonable backlog of unrelated cases which he takes up in chronological order and carries out expeditiously, that is sufficient. Work on a related case(s) that contributed substantially to the ultimate preparation of an application can be credited as diligence.).

Under 37 CFR 1.131, the critical period in which diligence must be shown begins just prior to the effective date of the reference or activity and ends with the date of a reduction to practice, either actual or constructive (i.e., filing a United States patent application). Note, therefore, that only diligence before reduction to practice is a material consideration. The "lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon" is not relevant to an affidavit or declaration under 37 CFR 1.131. See *Ex parte Merz*, 75 USPQ 296 (Bd. App. 1947). Form paragraph 7.62 (reproduced in MPEP § 715) may be used to respond to a 37 CFR 1.131 affidavit where diligence is lacking.

10. The evidence submitted is insufficient to establish diligence from a date of conception to an actual reduction to practice. There is no information provided in the exhibits explicitly demonstrate diligence applied to reduce the method to practice.

11. The included Declaration fails to properly describe the events/dates between alleged conception (prior to May 15, 2000) and indicated Actual Reduction to Practice (November 21, 2001). Applicant's sole evident that demonstrate the diligent are the marketing agreement dated back in July 7, 2000, and a letter dated back in September 24, 2000, which indicates a "final

documentation", which did not particular indicate what documentation could it be. Not a single act in the affidavits had demonstrated during the critical period of May 15, 2000 and Nov 21, 2000 that discuss/show the element of claiming invention.

12. Menzie discloses the amended limitations "Referring to Claims 1, 11, 19, 24, and 25, Menzie discloses at least one processor readable medium (refer to Col 5); instructions carried on the at least one medium (software program comprises instructions, refer to Col 5); wherein the instructions are configured to be readable from the at least one medium by at least one processor and thereby cause at least one processor to operate so as to: (refer to Col 4, Lines Col 5 and Col 18, Lines 35-55); Collecting outcomes data sets associated with one or more medical procedures (testing for autonomic nervous system, refer to Col 1, Lines 24) for a plurality of patients via one or more user interface (system is able to collect numerous patients/individuals information, Col 10, Lines 40-60, plurality of devices via the interface is able to collect per patient's information, refer to Col 4, Lines 1-15 and Col 4, Lines 37-39 and user interface, Col 4, lines 51); Converting at least some of the outcomes data sets associated with one or more medical procedures from the plurality of individuals into one outcomes results (test results, refer to Col 2, Lines 8-30 and Col 4, Lines 53-67, and Col 5, Lines 1-7); Establishing a norm based at least in part on an outcomes data group (refer to Col 7, Lines 30-31), the outcomes data group comprising a plurality of the outcomes data sets associated with one of the one or more medical procedures (refer to Col 2, Lines 25-60 and Col 6, Lines 60-67 and Col 7, Lines 1-35); Comparing a selected one of the at least one outcomes result to the norm (refer to Col 6, Lines 29-36 and 60-67, and Col 7, Lines 1-30); Generating at least one outcomes monitoring report comprising the selected one of the at

least one outcomes result and the norm (the result is able to view via a web browser, refer to Col 4, Lines 14-15). "

13. Kraf in view of Seare discloses all the amended limitations" Referring to Claims 1, 11, 19, 24, and 25, Kraft discloses at least one processor readable medium (refer to microprocessor, Col 12, Lines 30-35); Instructions carried on the at least one medium (software comprises instructions, refer to Col 5); Wherein the instructions are configured to be readable from the at least one carrier by at least one processor and thereby cause the at least one processor to operate so as to (refer to Col 14, Lines 5-20); Collecting outcomes data sets for a individual (refer to Col 13, Lines 45-67 and Col 4, Lines 52, system collecting data from patients/individuals, however, still collecting data per individual basis); Converting at least some of the outcomes data sets into at least one outcomes result (test results, refer to Col 13, Lines 45-67, Col 14, Lines 60-67 and Col 15, Lines 15-55); Establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the outcomes data sets associated with the one of the one or more medical procedures (refer to Col 20, Lines 30-55, and Col 13, Lines 45-67); Comparing a selected one of the at least one outcomes result to the norm (refer to Col 17, Lines 50-67 and Col 18, Lines 1-15, 30-67); Generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (refer to Col 13, Lines 45-67). Kraft discloses wherein the at least two outcomes data sets are surgical procedures outcomes data set (refer to Col 14, Lines 5-60).

Although Kraft disclosed the invention substantially as claimed, Kraft is silent regarding "collecting data from a plurality of individuals".

Seare, in an analogous art disclosed "collecting data from a plurality of individuals"(refer to Col 4, Lines 25-35).

Hence, providing features discloses by Seare, would be desired for a user to implement in order to allow comparison between individual treatment or a treatment group against a statistical norm or against a trend.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Kraft by including the features provided by Seare."

14. Brown in view of Seare discloses all the amended limitations "Brown discloses at least one processor readable medium (refer to Col 5); Instructions carried on the at least one carrier (the software program comprises instructions, refer to Col 5); wherein the instructions are configured to be readable from the at least one medium r by at least one processor and thereby cause at least one processor to operate so as to: (refer to Col 4, Lines Col 5 and Col 18, Lines 35-55); Collecting outcomes data sets for a plurality of patients associated with one or more medical procedures (refer to Col 1, Lines 30-50, system is able to collect numerous patients/individuals information, Col 10, Lines 40-60, and to monitor patient that have blood glucose, respiratory flow, and heart rate, refer to Col 1, Lines 57-67); Converting the outcomes data sets associated with one or more medical procedures for a plurality of individuals via one or more user interface (collecting information is via the interface, refer to Col 3, Lines 56, and refer to Col 2, Lines 8-30); Establishing a norm based at least in part on an outcomes data group (data being compared, and the norm is the medium which indicated on the graph, which including the data being collected, refer to Fig 10, which is between 70-120 MG/DL, and Col 17, Lines 50-67), the

outcomes data group comprising a plurality of the at least two outcomes data sets associated with the one of one or more medical procedures (refer to Col 2, Lines 25-60 and Col 6, Lines 60-67 and Col 7, Lines 1-35, refer to Fig 10, the norm is the mediums which indicated on the graphs,); Generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result (refer to Col); Brown discloses wherein the surgical procedures outcomes dataset are primary source data sets (refer to Col 8, Lines 45-56).

Although Kraft disclosed the invention substantially as claimed, Kraft is silent regarding "compare a selected one of the outcomes result to the norm";

Seare, in an analogous art, "discloses compare a selected one of the outcomes result to the norm" (refer to Col 4, Lines 25-35).

Hence, providing features disclosed by Seare, would be desirable for a user to implement in order to allow comparison between individual treatment or a treatment group against a statistical norm or against a trend.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Brown by including the features provided by Seare."

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Menzie et al hereinafter Menzie (US 6,650,932).

15. Referring to Claims 1, 11, 19, 24, and 25, Menzie discloses at least one processor readable medium (refer to Col 5); instructions carried on the at least one medium (software program comprises instructions, refer to Col 5); wherein the instructions are configured to be readable from the at least one medium by at least one processor and thereby cause at least one processor to operate so as to: (refer to Col 4, Lines Col 5 and Col 18, Lines 35-55); Collecting outcomes data sets associated with one or more medical procedures (testing for autonomic nervous system, refer to Col 1, Lines 24) for a plurality of patients via one or more user interface (system is able to collect numerous patients/individuals information, Col 10, Lines 40-60, plurality of devices via the interface is able to collect per patient's information, refer to Col 4, Lines 1-15 and Col 4, Lines 37-39 and user interface, Col 4, lines 51); Converting at least some of the outcomes data sets associated with one or more medical procedures from the plurality of individuals into one outcomes results (test results, refer to Col 2, Lines 8-30 and Col 4, Lines 53-67, and Col 5, Lines 1-7); Establishing a norm based at least in part on an outcomes data group (refer to Col 7, Lines 30-31), the outcomes data group comprising a plurality of the outcomes data sets associated with one of the one or more medical procedures (refer to Col 2, Lines 25-60 and Col 6, Lines 60-67 and Col 7, Lines 1-35); Comparing a selected one of the at least one outcomes result to the norm (refer to Col 6, Lines 29-36 and 60-67, and Col 7, Lines 1-30);

Generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (the result is able to view via a web browser, refer to Col 4, Lines 14-15).

16. Referring to Claims 2 and 12, Menzie discloses transmitting the at least two outcomes data sets associated with the one of the one or more medical procedures to a data processor (refer to Col 2, Lines 8-31, Col 4, Lines 50-67).

17. Referring to Claims 3, 5, 13, 15, and 21, Menzie discloses selectively restricting access to the at least one outcomes monitoring report (refer to Col 11, Lines 5-30).

18. Referring to Claims 4, and 14 and 20, Menzie posting the at least one outcomes monitoring report over the webpage (refer to Col 4 and 6).

19. Referring to Claim 6, Menzie discloses collecting the at least two outcomes data sets associated with the one or more medical procedures from at least one user entity at a plurality of discrete intervals (refer to Col 1, Col 2, Col 11, Lines 1-60, and Col 13, 14, and 16).

20. Referring to Claim 7, Menzie discloses generating the at least one outcomes monirtoring report from the plurality of discrete intervals (refer to Col 5 – 9, Col 1, 2, 11, Lines 1 – 60 , and Col 13, 14, and 16).

21. Referring to Claims 8 and 16, Menzie discloses collecting the outcomes data sets associated with the one or more medical procedures from a plurality of user entities (refer to Col 11, and Col 17),

individually identifying and converting the outcomes data sets associated with the one of the one or more medical procedures for each user entity of the plurality of user entities (refer to Col 11, Col 13, and 14),

and wherein the outcomes data sets from the plurality of user entities comprises the outcomes data group (refer to Col 11).

22. Referring to Claim 9 and 17, Menzie discloses wherein the at least one outcomes monitoring report includes at least one outcomes result for a selected user entity of the plurality of user entities and at least one comparison of the norm to the least one outcomes result for the selected user entity (refer to Col 5, 6, 7, 10, 14, 16, and 17).

23. Referring to Claims 10, and 18, Menzie discloses at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 1 (refer to Col 5, 12, 13, 15, and 18).

24. Referring to Claim 23, Menzie discloses wherein the surgical procedures outcomes dataset are primary source data sets (refer to Col 1 and 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-13, 15-19, and 21-23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft et al hereinafter Kraft (US 5,299,119) in view of Seare et al hereinafter Seare (US 6,223,164).

26. Referring to Claims 1, 11, 19, 24, and 25, Kraft discloses at least one processor readable medium (refer to microprocessor, Col 12, Lines 30-35); Instructions carried on the at least one medium (software comprises instructions, refer to Col 5); Wherein the instructions are configured to be readable from the at least one carrier by at least one processor and thereby cause the at least one processor to operate so as to (refer to Col 14, Lines 5-20); Collecting outcomes data sets for a individual (refer to Col 13, Lines 45-67 and Col 4, Lines 52, system collecting data from patients/individuals, however, still collecting data per individual basis); Converting at least some of the outcomes data sets into at least one outcomes result (test results, refer to Col 13, Lines 45-67, Col 14, Lines 60-67 and Col 15, Lines 15-55); Establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the outcomes data sets associated with the one of the one or more medical procedures (refer to Col 20, Lines 30-55, and Col 13, Lines 45-67); Comparing a selected one of the at least one outcomes result to the norm (refer to Col 17, Lines 50-67 and Col 18, Lines 1-15, 30-67); Generating at least one outcomes monitoring report comprising the selected one of the at least

one outcomes result and the norm (refer to Col 13, Lines 45-67). Kraft discloses wherein the at least two outcomes data sets are surgical procedures outcomes data set (refer to Col 14, Lines 5-60).

Although Kraft disclosed the invention substantially as claimed, Kraft is silent regarding "collecting data from a plurality of individuals".

Seare, in an analogous art disclosed "collecting data from a plurality of individuals"(refer to Col 4, Lines 25-35).

Hence, providing features discloses by Seare, would be desired for a user to implement in order to allow comparison between individual treatment or a treatment group against a statistical norm or against a trend.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Kraft by including the features provided by Seare.

27. Referring to Claims 2 and 12, Kraft discloses transmitting the outcomes data sets associated with the one of the one or more medical procedures to a data processor (refer to Col 14, Lines 5-67).

28. Referring to Claims 3, 5, 13, 15 and 21, Kraft discloses selectively restricting access to the at least one outcomes monitoring report (Operator is the one has access to report, refer to Col 15, Lines 20-67).

29. Referring to Claim 6, Kraft discloses collecting outcomes data sets associated with the one or more medical procedures from at least one user entity at a plurality of discrete intervals (refer to Col 13, Lines 45-67 and Col 4, Lines 52);

30. Referring to Claim 7, Kraft discloses generating the at least one outcomes monitoring report from at least two of the plurality of discrete intervals (refer to Col 14, Lines 5-60, Col 15, Lines 15-55).

31. Referring to Claims 8 and 16, Kraft discloses collecting the outcomes data sets associated with the one or more medical procedures from a plurality of user entities (refer to Col 14, Lines 5-60); individually identifying and converting the outcomes data sets associated with the one of the one or more medical procedures for each user entity of the plurality of user entities (refer to Col 14, Lines 60-67 and Col 15, Lines 1-55); and wherein the outcomes data sets associated with the one of the one or more medical procedures from the plurality of user entities comprises the outcomes data group (refer to Col 15, Lines 15-55).

32. Referring to Claim 9 and 17, Kraft discloses wherein the outcomes monitoring report includes at least one outcomes result for a selected user entity of the plurality of user entities and at least one comparison of the norm to the selected one of the least one outcomes result for the selected user entity (refer to Col 13, Lines 45-67, Col 14, Lines 60-67, Col 15, Lines 1-15).

33. Referring to Claim 10, and 18, Kraft discloses at least one processor readable medum for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in Claim 1 (refer to Col 15, Lines 1-15, Col 15, Lines 55-67, Col 16, Lines 1-30).

34. Referring to Claim 23, Kraft discloses wherein the at least two surgical procedures outcomes dataset are primary source data sets (refer to Col 14, Lines 5-60).

Claims 4, 14, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft et al hereinafter Kraft (US 5,299,119) in view of Seare et al hereinafter Seare (US 6,223,164) and in further view of Killcommons et al hereinafter Killcommons (US 6,424,996).

36. Referring to Claims 4, and 14 and 20, Kraft posting the outcomes monitoring report (refer to Col 15, Lines 20-66).

Although Kraft and Seare disclosed the invention substantially as claimed, Kraft and Seare are silent regarding "posting the at least one outcomes report on the webpage over the webpage". Killcommons, in an analogous art discloses "posting the at least one outcomes report on the webpage over the webpage" (refer to Col 4 and 6).

Hence, providing features disclosed by Killcommons, would be desirable for a user to implement since the features provided by Killcommons allow flexibility in term of remote accessing the system.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Kraft and Seare by including the features provided by Killcommons.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al hereinafter Brown (US 6,101,478) in view of Seare et al hereinafter Seare (US 6,223,164).

37. Referring to Claims 1, 8, 9, 11, 16, 17, 19, 24, and 25, Brown discloses at least one processor readable medium (refer to Col 5); Instructions carried on the at least one carrier (the software program comprises instructions, refer to Col 5); wherein the instructions are configured to be readable from the at least one medium r by at least one processor and thereby cause at least one processor to operate so as to: (refer to Col 4, Lines Col 5 and Col 18, Lines 35-55); Collecting outcomes data sets for a plurality of patients associated with one or more medical procedures (refer to Col 1, Lines 30-50, system is able to collect numerous patients/individuals information, Col 10, Lines 40-60, and to monitor patient that have blood glucose, respiratory flow, and heart rate, refer to Col 1, Lines 57-67); Converting the outcomes data sets associated with one or more medical procedures for a plurality of individuals via one or more user interface

(collecting information is via the interface, refer to Col 3, Lines 56, and refer to Col 2, Lines 8-30); Establishing a norm based at least in part on an outcomes data group (data being compared, and the norm is the medium which indicated on the graph, which including the data being collected, refer to Fig 10, which is between 70-120 MG/DL, and Col 17, Lines 50-67), the outcomes data group comprising a plurality of the at least two outcomes data sets associated with the one of one or more medical procedures (refer to Col 2, Lines 25-60 and Col 6, Lines 60-67 and Col 7, Lines 1-35, refer to Fig 10, the norm is the mediums which indicated on the graphs,); Generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result (refer to Col); Brown discloses wherein the surgical procedures outcomes dataset are primary source data sets (refer to Col 8, Lines 45-56).

Although Kraft disclosed the invention substantially as claimed, Kraft is silent regarding "compare a selected one of the outcomes result to the norm";

Seare, in an analogous art, "discloses compare a selected one of the outcomes result to the norm" (refer to Col 4, Lines 25-35).

Hence, providing features disclosed by Seare, would be desirable for a user to implement in order to allow comparison between individual treatment or a treatment group against a statistical norm or against a trend.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Brown by including the features provided by Seare.

38. Referring to Claims 2 and 12, Brown discloses transmitting the at least two outcomes data sets associated with the one of the one or more medical procedures to a data processor (refer to Col 13, Lines 37).

39. Referring to Claims 3, 5, 13, 15, and 21, Brown discloses selectively restricting access to the at least one outcomes monitoring report (refer to Col 14, Lines 27).

40. Referring to Claims 4, and 14 and 20, Brown posting the at least one outcomes monitoring report over the webpage (refer to Col 4, Lines 15-20 and Col 6, Lines 5-15).

41. Referring to Claim 6, Brown discloses collecting the at least two outcomes data sets associated with the one or more medical procedures from at least one user entity at a plurality of discrete intervals (refer to Col 8, Lines 55-67).

42. Referring to Claim 7, Brown discloses generating the at least one outcomes monitoring report from the plurality of discrete intervals (refer to Col 8, Lines 55-67).

43. Referring to Claims 10, and 18, Brown discloses at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 1 (refer to Col 8, Lines 19-34).

44. Referring to Claim 22, Brown discloses wherein the outcomes data sets are surgical procedures outcomes data set (refer to Col 8, Lines 45-56).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant is reminded that in amending in response to a rejection of claims, the patentable novelty must be clearly shown in view of the state of the art disclosed by the references cited and the objection made. Applicant must show how the amendments avoid such references and objections. See 37 CFR 1.111(c).

Examiner's Notes: Examiner has cited particular columns and line numbers in the references applied to the claims above for the convenience of the applicant. Although the specified citations are representative of the teachings of the art and are applied to specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested from the applicant in preparing responses, to fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner. In the case of amending the claimed invention, Applicant is respectfully requested to indicate the portion(s) of the specification which dictate(s) the structure relied on for proper interpretation and also to verify and ascertain the metes and bounds of the claimed invention.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen C. Tang whose telephone number is (571)272-3116. The examiner can normally be reached on M-F 7 - 3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Follansbee can be reached on (571)272-3964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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